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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
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10/666,486

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Stewart Shuman

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23432 7590 04/14/2009  
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EXAMINER

BHAT, NARAYAN KAMESHWAR

ART UNIT

PAPER NUMBER

1634

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**Please find below and/or attached an Office communication concerning this application or proceeding.**

The time period for reply, if any, is set in the attached communication.

<b>Office Action Summary</b>	<b>Application No.</b> 10/666,486	<b>Applicant(s)</b> SHUMAN ET AL.	
	<b>Examiner</b> NARAYAN K. BHAT	<b>Art Unit</b> 1634	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

### Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

### Status

- 1) ☒ Responsive to communication(s) filed on 08 January 2009.
- 2a) ☒ This action is **FINAL**.                      2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

### Disposition of Claims

- 4) ☒ Claim(s) 45, 79-95 and 98-100 is/are pending in the application.
- 4a) Of the above claim(s) \_\_\_\_\_ is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 45, 79-95 and 98-100 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

### Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

### Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All    b) ☐ Some \*    c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
  2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
  3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

### Attachment(s)

- |  |   |
|--|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892)          | 4) <input type="checkbox"/> Interview Summary (PTO-413)           |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | Paper No(s)/Mail Date. _____                                      |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08)          | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| Paper No(s)/Mail Date _____  | 6) <input type="checkbox"/> Other: _____                          |

### **FINAL ACTION**

1. This office action is written in reply to applicant's correspondence filed January 8, 2009. Claims 45, 79, 90, 92, 93, 95, 98 and 100 were amended. Claims 96 and 97 were cancelled. Applicant's amendments requiring attaching a double stranded DNA tag to the 5' end of the isolated mRNA and synthesizing the cDNA using the DNA-tagged mRNA with reverse transcriptase necessitated the new grounds of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL.**

### ***Claim Status***

2. Claims 45, 79-95 and 98-100 are pending in this application and are under prosecution.
3. Applicants arguments filed on October 9, 2008 have been fully considered and addressed following claim rejections.

### ***Amendments to Claims***

4. Amendments to the claims 45, 79, 90, 92, 93, 95, 98 and 100 have been reviewed and entered.

### ***Nucleic Acid Sequence Listing***

5. Sequence listing submitted by Applicants on January 8, 2009 has been reviewed and entered. It is also noted that sequence listing submitted on CD has been accepted by STIC.

### ***Specification***

6. Amendments to the specification to correct the SEQ ID NOS. in Figure 11 have been reviewed and entered.

### ***Claim Rejections - 35 USC § 112***

7. Previous rejection of claim 79 has been withdrawn in view of claim amendments.

### ***Double Patenting***

8. The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the "right to exclude" granted by a patent and to prevent possible harassment by multiple assignees. A nonstatutory obviousness-type double patenting rejection is appropriate where the conflicting claims are not identical, but at least one examined application claim is not patentably distinct from the reference claim(s) because the examined application claim is either anticipated by, or would have been obvious over, the reference claim(s). See, e.g., *In re Berg*, 140 F.3d 1428, 46 USPQ2d 1226 (Fed. Cir. 1998); *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); *In re Van Ornum*, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970); and *In re Thorington*, 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

A timely filed terminal disclaimer in compliance with 37 CFR 1.321(c) or 1.321(d) may be used to overcome an actual or provisional rejection based on a nonstatutory double patenting ground provided the conflicting application or patent either is shown to be commonly owned with this application, or claims an invention made as a result of activities undertaken within the scope of a joint research agreement.

Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).

9. Claims 45, 79-95 and 98-100 are rejected on the ground of nonstatutory obviousness-type double patenting as being unpatentable over claims 1-17 of U.S.

Patent No. 6,653,106 in view of Carninci et al (Genomics, 1996, 37, 327-336). Although

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the conflicting claims are not identical, they are not patentably distinct from each other because of the following reasons.

Regarding instant claims 45 and 79, claims 7 and 13 of the patent '106 are drawn to a method of obtaining a cDNA corresponding to a gene, the method comprising: (a) contacting a sequence-specific type I DNA topoisomerase in vitro with a double-stranded DNA whose first strand is to be covalently joined to an mRNA strand corresponding to the gene, (b) contacting the resulting complex in vitro with a 5'OH-containing mRNA strand corresponding to the gene and having a 5' terminal portion complementary to the 3' terminal portion of the DNA 5' tail, under conditions permitting (i) the mRNA strand to hybridize with the 5' tail and (ii) the topoisomerase to covalently join the mRNA strand and first DNA strand, thereby covalently joining the DNA strand to the mRNA strand; and (c) producing cDNA using as a template the covalently joined mRNA and DNA strands resulting from step (b), thereby obtaining a cDNA corresponding to the gene. Claim 13 of the patent '106 are drawn to a method of generating 5'-OH mRNA by decapping native mRNA. The native mRNA containing the cap is interpreted as full-length mRNA.

Claims 1 and 2 of the '106 patent are drawn to double stranded DNA having structural features recited in instant claim 45 and therefore obvious to synthesize oligonucleotide having sequences recited in SEQ ID NO. 30 and 31 as recited in instant claim 79 to attach double stranded DNA to the 5' end of the mRNA.

Regarding claims 80-84 and 99-100, claims 1-17 of the patent '106 are not drawn to isolating mRNA using affinity purification material and inserting the amplified cDNA

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into an expression vector. However, affinity purification of mRNA and inserting cDNA into an expression vector were known in the art at the time of the claimed invention was made as taught by Carninci et al.

Carninci et al teaches a method to isolate full length mRNA comprising biotin moiety (i.e., an affinity purification tag) tagged to cap structure of mRNA (Fig. 1B, see the legend for details, pg. 328, column 1, paragraph 2). Carninci et al also teaches that the biotin moiety (i.e., affinity purification material) is captured on magnetic porous particles (i.e., solid support) coated with streptavidin (Fig. 1C, Steps 1-3, See the legend for details, pg. 328, column 2, paragraph 3). Carninci et al further teaches that mRNA is decapped by chemical treatment, wherein the chemical treatment is periodate oxidation and eliminates the covalent bond between diol groups (Fig. 1B, pg. 334, column 1, paragraphs 2 and 3), which is reasonably interpreted as beta elimination because instant specification does not provide limiting definition for beta elimination. Carninci et al also teaches inserting the amplified cDNA into an expression vector (Fig. 1C).

Carninci et al also teaches that affinity purification of mRNA with tagged cap structure produces high content full length cDNA library with over 95% full length clones with an unbiased representation of the starting mRNA population (Abstract).

It would be have been prima facie obvious to one having the ordinary skill in the art at the time the invention was made to modify the mRNA tagging method of claim 7 of '106 patent with the affinity tagged mRNA cap structure method of Carninci et al.

One having the ordinary skill in the art would have been motivated to modify the mRNA tagging method of claim 7 of '106 patent with a reasonable expectation of

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success with the expected benefit of producing high content full length cDNA library with over 95% full length clones with an unbiased representation of the starting mRNA population as taught by Carninci et al (Abstract).

It is also noted that claims 1-17 of the '106 patent are drawn to the additional limitations required by instant dependent claims 85-95 and 98. Therefore dependent claims 80-95 and 98-100 are also obvious for the same reasons as described above for instant claims 45 and 79 over claims 1-17 of '106 patent in view of Carninci et al.

### ***Allowable Subject Matter***

10. With respect to claims 45, 79-95 and 98-100, the prior art of Kato et al (Fig. 1B) and Schafer (Fig. 1c) teach attaching single stranded RNA/DNA mixed oligonucleotide to the 5' end of the full length mRNA by T4 RNA ligase. The prior art of record do not teach attaching a double stranded DNA comprising a covalently linked topoisomerase to the 5' end of a full length mRNA. The prior art of the record also do not teach the said double stranded DNA further comprising a 5' strand (i.e., upper strand) having tail at the 5' end and the 3' strand (i.e., lower strand) having a 1 to 4 nucleotide overhang at its 5' end, which is complementary to the 5' end of the full length mRNA. Furthermore, the elected SEQ ID NOS. 30 and 31 as the double stranded DNA tag in instant claims 79 and 95 are taught by the 6,653,106 patent, which is not a prior art because the instant application is the continuation of the '106 patent. Therefore subject matter of the instant claims 45, 79-95 and 98-100 are free of the prior art of record.

***Response to remarks from the Applicants***

***Claim rejections under 35 U.S.C. § 102(b)***

11. Applicant's arguments with respect to claims 45, 80, 85-89, 91 and 100 being anticipated by Kato et al have been fully considered but are moot in view of withdrawn rejections (Remarks, pgs. 8-9).

***Claim rejections under 35 U.S.C. § 103(a)***

12. Applicant's arguments with respect to claims 45, 81-84, 87, 88 and 90 as being unpatentable over Kato et al and Carninci et al have been fully considered but are moot in view of withdrawn rejections (Remarks, pgs. 10-11). Applicant's arguments with respect to teachings of Carninci et al as it pertains to the rejections made in this office action are addressed below.

Applicants argue that Carninci et al do not teach chemical decapping of the mRNA (Remarks, pg. 10, paragraph 3). This argument is not persuasive because Carninci et al teaches chemical treatment comprises periodate oxidation (Fig. 1B), which is defined as decapping of mRNA as defined in the instant claim 90. As described above in section 10, Carninci et al teaches that periodate oxidation eliminates the covalent bond between diol groups of the cap structure of the mRNA (Fig. 1B, pg. 334, column 1, paragraphs 2 and 3), which is reasonably interpreted as beta elimination because instant specification does not provide limiting definition for beta elimination. Since Carninci et al teach periodate oxidation and beta elimination, arguments are not persuasive.



Applicant's arguments with respect to claims 45 and 92-95 as being unpatentable over Kato et al and Shuman have been fully considered but are moot in view of withdrawn rejections (Remarks, pg. 11).

Applicant's arguments with respect to claim 79 as being unpatentable over Kato et al, Shuman and Chenchick et al have been fully considered but are moot in view of withdrawn rejections (Remarks, pg. 12).

### ***Double Patenting***

13. Nonstatutory obviousness-type double patenting rejection of claims 45, 79-95 and 98-100 of instant application over claims 1-17 of '106 patent in view of Carninci et al has been maintained because it is the only rejection remaining over the instant claims. It is also noted that Applicants is considering filing a terminal disclaimer if the ODP is the only rejection remaining over instant claims (Remarks, pg. 13).

### ***Conclusion***

14. No claims are allowed.

15. Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within

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TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Narayan K. Bhat whose telephone number is (571)-272-5540. The examiner can normally be reached on 8.30 am to 5 pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Ram R. Shukla can be reached on (571)-272-0735. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a

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USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/Narayan K. Bhat/

Examiner, Art Unit 1634

/Ram R. Shukla/

Supervisory Patent Examiner, Art Unit 1634